APPENDIX Q

# Collaborative research Ceding to an External IRB

**DU IRB may cede to an external IRB if one of the following criteria is met**:

* Meets a sponsor requirement
* The external entity is the award recipient
* The Principal Investigator is not affiliated with DU (i.e., is affiliated with the external entity)
* The external investigator(s) is assuming more of the responsibilities/risk of the research

**Ceding will NOT be approved by DU if any of the following criteria are met**:

* The research is a collaboration with an international entity (each IRB must review)
* The external IRB/entity has not agreed to serve as the IRB of record (each IRB must review)
* The research project has been determined or qualifies for exempt level review (each IRB must review)
* The DU investigator is not ‘engaged’ in the research (e.g., recruitment that involves talking with potential participants about the study, obtaining consent/assent, interaction with participants during their participation, access to or use of identifiable data, etc.)

**INSTRUCTIONS** for requesting **DU to cede to an external IRB** to serve as the IRB of Record for a collaborative project:

* Create a new project in IRBNet. See instructions [here](https://www.du.edu/orsp/research-compliance/content/irbnet).
* Submit this form (Appendix Q), along with any other required documents, including:
* IRB Authorization Agreement (IAA) or ceding/reliance agreement from external entity
* IRB Approval Letter from external IRB for collaborative project
* External study protocol/IRB application
* External informed consent forms
* Certificates of all [CITI training](https://www.du.edu/orsp/research-compliance/human-subject-research/training-requirements) for human subjects’ protection for all DU investigators
* Any Data Use Agreements (DUAs) if applicable
* Make sure that your Financial Conflict of Interest (FCOI) Disclosure is updated to include any considerations for this project

## Section A: Investigator information

A.1 **DU Investigator:** Click here to enter text. Credentials: Click here to enter text.

#####

DU Dept./College: Click here to enter text.

#####

DU Investigator email: Click here to enter text.

Title of this collaborative project: Click here to enter text.

A.2 **External non-DU investigator**: Click here to enter text. Credentials: Click here to enter text.

Non-DU investigator Institution: Click here to enter text.

Non-DU Investigator email: Click here to enter text.

 Name of external IRB: Click here to enter text.

External Federalwide Assurance (FWA) #: Click here to enter text.

External IRB Registration #: Click here to enter text.

External IRB Administrator Contact: Click here to enter text.

Email of external IRB Contact (if different than Administrator Contact): Click here to enter text.

A.3 **Financial Conflict of Interest**. Does any member of the DU team have ownership of other Significant Financial Interest (SRI) with this research as defined by HRPP Policy 301?

[ ]  No [ ]  Yes

If yes, has the Office of Research Integrity & Education made a decision regarding this SFI as it pertains to this proposed research?

 [ ]  Yes [ ]  No

If no, contact the ResearchFCOI@du.edu to establish a management plan

A.4 **Performance Sites:** Click here to enter text.

## Section B: IRB Reliance Information

B.1 Why are you seeking to rely on another IRB? Check all that apply.

[ ]  In order to comply with the NIH single IRB (sIRB) policy

[ ]  In order to meet another, non-NIH, sponsor’s requirement

[ ]  It is required by another institution engaged in the research

[ ]  Another institution is conducting most of the research

[ ]  Other: Click here to enter text.

If you have checked any boxes above, has the external IRB already agreed that it can conduct review on behalf of DU?

[ ]  Yes [ ]  No

*If you do not have confirmation that the external IRB will review on behalf of DU, do not submit this application. If the external IRB cannot review on behalf of DU, you will need to complete an application through IRBNet for review by the DU IRB.*

B.2 Is this study related to an existing application and/or study or series of studies reviewed by either the DU IRB or an external IRB?

*For example, a new sub-study for a study currently reviewed by an external IRB or a study currently under review by the DU IRB that you are requesting be transferred to an external IRB. If you are requesting a transfer from one IRB to another contact the DU IRB Office before submitting this form.*

[ ]  No [ ]  Yes

If yes, briefly describe the relationship of those studies to this one and list the DU study PI and IRBNet number. Click here to enter text.

## Section C: Funding

C.1. Study sponsor name: Click here to enter text.

*(if none, put “n/a”)*

C.2 Sponsor protocol number or grant number: Click here to enter text.

*(if none, put “n/a”)*

C.3 Name of awardee on the funding source. Click here to enter text.

C.4 Institution that is receiving the funds:

Click here to enter text.

C.5 Will DU be a sub-recipient of the grant or funding source?

[ ]  Yes [ ]  No

If yes, list the DU Sponsored Programs Administrator assigned to this project:

Click here to enter text.

C.6 Does this study involve more than one organization or institution, meaning that more than one organization or institution is engaged in the research?

[ ]  Yes [ ]  No

*The DU IRB can only provide authorization for the external IRB to review on behalf of DU. If other organizations are involved in the research, those organizations must also authorize any external IRB to conduct review on their behalf.*

##  Section D: Study Activities Conducted by DU Research Team

D. 1 Which of the following activities will be conducted by the **DU investigator(s)**? Check all that apply:

[ ]  Obtain consent and/or assent

[ ]  Perform research procedures

[ ]  Administer study interventions

[ ]  Obtain, use, or analyze identifiable data and/or specimens

[ ]  Obtain, use, or analyze de-identifiable data and/or specimens

[ ]  Other participant contact

[ ]  Other responsibilities or roles

 If other, please briefly explain: Click here to enter text.

D. 2 Identify any of these populations that DU will recruit:

[ ]  Children

[ ]  Pregnant women/fetuses

[ ]  Prisoners

[ ]  Native Americans/Alaska Natives

[ ]  Cognitively impaired adults

[ ]  Other unique populations

If other, please briefly explain: Click here to enter text.

D.3 Is it reasonably foreseeable that you may obtain information from subjects about abuse or neglect of children and/or vulnerable adults?

[ ]  No [ ]  Yes

If yes, briefly explain: Click here to enter text.

If YES, has a mandatory reporting statement been included as part of the informed consent?

[ ]  No [ ]  Yes

## Section E: Transferring Data

**Data Transfer/Use Agreement**
A data transfer agreement is a contract governing the transfer of data, including human subject data, between institutions for the purposes of research.

E.1 Will this collaborative project receive or send data?

[ ]  No [ ]  Yes

If **Yes**, a Data Agreement Request Form is needed to determine the type and scope of data to be used or transferred. Please complete the Office of Intellectual Property and Technology Transfer (OIPTT) intake form [here](https://tinyurl.com/3cme62am).